**Citation:**

Tuthill RW, Calabrese EJ. The Massachusetts Blood Pressure Study, Part 4. Modest sodium supplementation and blood pressure change in boarding school girls. *Toxicol Ind Health.* 1985 Sep; 1(1): 35-43.

**PubMed ID:** 3842545

**Study Design:**

Randomized control trial

**Class:**

A - Click here for explanation of classification scheme.

**Research Design and Implementation Rating:**

POSITIVE: See Research Design and Implementation Criteria Checklist below.

**Research Purpose:**

To determine if a small amount of sodium supplementation with food or water influenced blood pressure (BP) in a group of female high school students.

**Inclusion Criteria:**

Ninth through twelfth grade girls enrolled in a private boarding school with informed consent of both the girls and their parents.

**Exclusion Criteria:**

- One or more of consulting project physicians consider the student at risk if exposed to extra salt
- If the student had medical condition or took medication that might affect their blood pressure.

**Description of Study Protocol:**

**Recruitment**

Students from a private boarding school were asked to participate in the study.

**Design**

Randomized control study.

**Blinding Used**

Both students and technicians were blinded.

**Intervention**

- Baseline data was collected for one week prior to supplementation
- All subjects took four capsules twice per day, under supervision for eight weeks (four 0.5g sodium capsules were given to the treatment group daily)
- Group one received a placebo twice a day, group two received a two grams of salt capsules midmorning and a placebo in the evening; group three received a placebo in the morning and two grams of salt capsules in the evening
- Blood pressure measurements were taken after dinner before capsules and a 24-hour urine collection was done on the same day twice a week for each student.

**Statistical Analysis**

Repeated measures analysis of variance for BP readings and repeated measures of variance for baseline values and all study variables were examined using covariance analysis to identify any negative confonders that might mask effect.

**Data Collection Summary:**

**Timing of Measurements**

- Blood pressure measurements were taken after dinner before capsules were taken twice a week for each student
- 24-hour urine collections were collected for the 24 hours prior to when BP was taken
- Immediately after BP readings were taken, a checklist of potentially stressful events was completed.

**Dependent Variables**

Variable 1: BP was measured by two technicians who were blinded to each other's readings.

**Independent Variables**

- Two grams sodium were administered in capsules either mid-morning (water group) or immediately following evening meal (food group); alternate dose time received dextrose capsules
- Control group received dextrose placebos both mid-morning and after evening meal.

**Control Variables**

- 24 hour urine samples were collected twice a week
- A checklist of stressful events was completed twice a week.

**Description of Actual Data Sample:**

- *Initial N:*
    - Campus 1
        - Students available: 254
        - Students that agreed to participate: 121
        - Students that completed: 107 (94.6%)
    - Campus 2:
        - Students available: 294

- Students that agreed to participate: 95
- Students that completed: 84 (92.3%)

- *Age:* Females ninth to 12th grade, actual ages were not stated
- *Other relevant demographics:* These were girls from a private boarding school; one might assume an upper socio-economic status, most likely with little ethnic diversity given study publication date (1985)
- *Location:* Publishing authors from University of Massachusetts, Amhurst, MA.

**Summary of Results:**

**Key Findings**

- There were no significant (NS) differences in systolic BP (SBP) or diastolic BP (DBP) measurements between study and control groups (mean differences were in the order of 1.4mmHg at maximum)
- There was NS relationship between SBP and DBP and level of sodium supplementation (0.8g per day).

**Other Findings**

- All groups experienced a rise in both SBP the first few weeks of the study
- 24-hour urine collections verified desired sodium differential between study and control groups
- Stress measures were not related to BP change.

**Author Conclusion:**

The authors conclude that there was NS relationship between sodium supplementation (0.8g daily) and BP over the eight-week study.

Possible explanations posed by the authors:

- There is no relationship between sodium intake and BP: Since other research suggests that at least some individuals are salt sensitive, they suggest that other elements besides sodium such as calcium, cadmium, barium and zinc might play a role and these were not measured in the study
- Lack of compliance with capsule, BP and urine specimen regimes: Seven dropouts and six low compliers were eliminated from the analysis and were at least 89.5% to 98.3% for capsule sessions and BP measurements, urine collections
- Sodium supplement effect was swamped out by variation in sodium from food sources; however, sodium supplement groups were similar in urine sodium excretion and distinct from the placebo group on both campuses. The rapid rise in SBP experienced by all groups during the same time period correlated with a higher sodium excretion rate for all groups.
- Sodium supplement was not large enough to elicit a significant difference in BP
- Lack of statistical power: Given the sample size, only a 2.5mmHg BP difference would be detectable.

***Reviewer Comments:***

***Strengths***

- *Double-blind intervention design*
- *Large sample size.*

***Limitations***

- *Age and anthropometrics were not reported; however, both the mean SBP and DBP of all groups were very close to the 50th percentile for age group inclusive at baseline*
- *Lack of statistical power: The major problem with this study is that the authors intended to combine the two campus' data and the power to determine a difference of 1.5mmHg would have required the total data set to be combined. The authors state that it was not possible to do this because campus one and two were different in some way. This is not entirely clear from the manuscript but may have been that one was evaluated in fall semester and the second in the following semester.*

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***Research Design and Implementation Criteria Checklist: Primary Research***

| **Relevance Questions** | | |
|---|---|---|
| 1. | Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies) | Yes |
| 2. | Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about? | Yes |
| 3. | Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice? | Yes |
| 4. | Is the intervention or procedure feasible? (NA for some epidemiological studies) | Yes |

| **Validity Questions** | | |
|---|---|---|
| **1.** | **Was the research question clearly stated?** | Yes |
| 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| 1.3. | Were the target population and setting specified? | Yes |
| **2.** | **Was the selection of study subjects/patients free from bias?** | Yes |
| 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| 2.2. | Were criteria applied equally to all study groups? | Yes |

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|---|---|---|
| 2.3. | Were health, demographics, and other characteristics of subjects described? | No |
| 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |
| **3.** | **Were study groups comparable?** | Yes |
| 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | Yes |
| 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |
| 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | Yes |
| **4.** | **Was method of handling withdrawals described?** | Yes |
| 4.1. | Were follow-up methods described and the same for all groups? | No |
| 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| 4.4. | Were reasons for withdrawals similar across groups? | ??? |
| 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | Yes |
| **5.** | **Was blinding used to prevent introduction of bias?** | Yes |
| 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | Yes |
| 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |

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| 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | Yes |
| **6.** | **Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?** | Yes |
| 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |
| 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
| 6.3. | Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect? | Yes |
| 6.4. | Was the amount of exposure and, if relevant, subject/patient compliance measured? | Yes |
| 6.5. | Were co-interventions (e.g., ancillary treatments, other therapies) described? | N/A |
| 6.6. | Were extra or unplanned treatments described? | N/A |
| 6.7. | Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? | N/A |
| 6.8. | In diagnostic study, were details of test administration and replication sufficient? | Yes |
| **7.** | **Were outcomes clearly defined and the measurements valid and reliable?** | Yes |
| 7.1. | Were primary and secondary endpoints described and relevant to the question? | Yes |
| 7.2. | Were nutrition measures appropriate to question and outcomes of concern? | ??? |
| 7.3. | Was the period of follow-up long enough for important outcome(s) to occur? | N/A |
| 7.4. | Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? | Yes |
| 7.5. | Was the measurement of effect at an appropriate level of precision? | Yes |
| 7.6. | Were other factors accounted for (measured) that could affect outcomes? | Yes |
| 7.7. | Were the measurements conducted consistently across groups? | Yes |
| **8.** | **Was the statistical analysis appropriate for the study design and type of outcome indicators?** | Yes |

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|---|---|---|
| 8.1. | Were statistical analyses adequately described and the results reported appropriately? | Yes |
| 8.2. | Were correct statistical tests used and assumptions of test not violated? | Yes |
| 8.3. | Were statistics reported with levels of significance and/or confidence intervals? | Yes |
| 8.4. | Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? | N/A |
| 8.5. | Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? | Yes |
| 8.6. | Was clinical significance as well as statistical significance reported? | Yes |
| 8.7. | If negative findings, was a power calculation reported to address type 2 error? | Yes |
| **9.** | **Are conclusions supported by results with biases and limitations taken into consideration?** | Yes |
| 9.1. | Is there a discussion of findings? | Yes |
| 9.2. | Are biases and study limitations identified and discussed? | Yes |
| **10.** | **Is bias due to study's funding or sponsorship unlikely?** | Yes |
| 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| 10.2. | Was the study free from apparent conflict of interest? | Yes |